

07-14-04

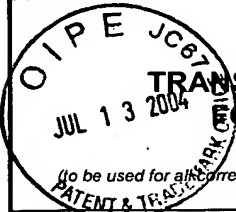
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PTO/SB/21 (03-03)

Approved for use through 4/30/2003. OMB 0651-0031

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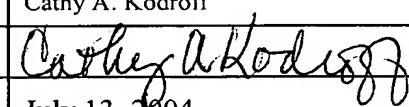
	Application Number	10/823,973	
	Filing Date	April 14, 2004	
	First Named Inventor	Gibbons et al	
	Group Art Unit		
	Examiner Name		
Total Number of Pages in this Submission	9	Attorney Docket Number	AM-101323USA

### ENCLOSURES (check all that apply)

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### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual Name	HOWSON AND HOWSON Cathy A. Kodroff
Signature	
Date	July 13, 2004

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AM101323USA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appln. No. : 10/823,973 Confirmation No. :  
Applicant : Gibbons et al  
Filed : April 14, 2004  
Art Unit :  
Examiner :  
Customer No. : 38199  
Title : ANTINEOPLASTIC COMBINATIONS

Mail Stop Amendment  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Applicant submits to the Examiner the attached Form PTO/SB/08A/B document listing and this paper pursuant to 37 CFR § 1.56 and § 1.97-1.98. Form PTO/SB/08A/B is attached and a copy of the documents are enclosed herewith. This Information Disclosure Statement is submitted within three months from the filing date of this application and before the receipt of a first Office Action on the merits. Therefore, no fees are believed due.

The Director is hereby authorized to charge any deficiency in any fees due with the filing of this paper or credit any overpayment in any fees to our Deposit Account Number 08-3040.

## REMARKS

Listed below are previously filed, co-pending, U.S. patent applications. These applications and the present application are commonly owned:

Copies of these applications with their claims as filed are provided.


- (1) U.S. Patent Application No. 10/374,644, February 26, 2003
- (2) U.S. Patent Application No. 10/212,889, August 6, 2002, U.S. Patent No. 6,617,333, issued on September 9, 2003
- (3) U.S. Patent Application No. 10/116,902, April 5, 2002, publication No. US-2002-0183239-A1, December 5, 2002
- (4) U.S. Patent Application No. 10/117, 161, April 5, 2002, publication No. US-2002-0183240-A1, December 5, 2002
- (5) U.S. Patent Application No. 10/157,275, May 29, 2002, republished as US-2002-0198137-A1, December 26, 2002
- (6) U.S. Patent Application No. 10/790,488, March 1, 2004

Item [CC] is in German, and relates to a compound useful for immunosuppression. A translation is provided in item [DD].

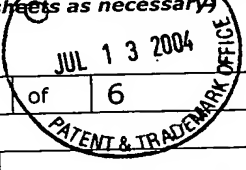
The Examiner is respectfully requested to consider the enclosed documents identified in this paper and in the attached Form PTO/SB/08A/B during the course of examination of this application.

Respectfully submitted,

HOWSON AND HOWSON  
Attorneys for Applicant

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				Group Art Unit				
				Examiner Name				
Sheet 1 of 6		Attorney Docket Number		AM-101323USA				
U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	A	US-3,929,992		12-30-1975	Sehgal et al			
	B	US-3,993,749		11-23-1976	Sehgal et al			
	C	US-4,401,653		08-30-1983	Chee P.Eng			
	D	US-5,078,999		01-07-1992	Warner et al			
	E	US-4,885,171		12-05-1989	Surendra et al			
	F	US-5,080,899		01-14-1992	Sturm et al			
	G	US-5,100,899		03-31-1992	Sir R. Calne			
	H	US-5,362,718		11-08-1994	Skotnicki et al			
	I	US-5,321,009		06-14-1994	Baeder et al			
	J	US-5,206,018		04-27-1993	Sehgal et al			
	K	US-5,286,730		02-15-1994	Caufield et al			
	L	US-5,286,731		02-15-1994	Caufield et al			
	M	US-5,288,711		02-22-1994	Mitchell et al			
	N	US-5,387,589		02-07-1995	Prasad S. Kulkarni			
	O	US-5,496,832		03-05-1996	Jay J. Armstrong			
	P	US-5,516,781		05-14-1996	Morris et al			
	Q	US-5,561,138		10-01-1996	Jay J. Armstrong			
	R	US-5,665,772		09-09-1997	Cottens et al			
	S	US-6,277,983		08-21-01	Shaw et al			
	T	US-5,728,710		03-17-1998	Luengo			
FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> - Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	U	EP	0525960	A1	03-02-1993	Miller		
	V	PCT	WO 02/066019	A2	08-29-2002	Novartis AG		
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				Filing Date	April 14, 2004
				First Named Inventor	Gibbons et al
				Group Art Unit	
				Examiner Name	
Sheet	3	of	6	Attorney Docket Number	AM101323USA

**OTHER PRIOR ART-NONPATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item, (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), column(s), number(s), publisher, city and/or country where published	T <sup>2</sup>
	FF	<b>SEHGAL ET AL</b> , Rapamycin (AY-22, 989), A New Antifungal Antibiotic, II. Fermentation, Isolation and Characterization, The Journal of Antibiotics, Vol. XXVIII No. 10, pp. 727-732 (October 1975)	
	GG	<b>CALNE ET AL</b> , Prolonged Survival of Pig Orthotopic Heart Grafts Treated with Cyclosporin A, The Lancet, pp. 1183-1185 (June 3, 1978)	
	HH	<b>BAKER ET AL</b> , Rapamycin (AY-22,989), A New Antifungal Antibiotic, III. In Vitro and In Vivo Evaluation, The Journal of Antibiotics, Vol. XXXI, No. 6, pp. 539-545, (June 1978)	
	II	<b>MARTEL ET AL</b> , Inhibition of the Immune Response by Rapamycin, a New Antifungal Antibiotic, Can. J. Physiol. Pharmacol. Vol.55, pp. 48-51 (1977)	
	FF	<b>VEZINA ET AL</b> , Rapamycin (AY-22,989) A new Antifungal Antibiotic, I. Taxonomy of the Producing Streptomycete and Isolation of the Active Principle, The Journal of Antibiotics, pp. 721-726 (October 1975)	
	GG	<b>DUMONT ET AL</b> , Rapamycin Blocks the Immunosuppressive Effect of FK506 But Not That of Cyclosporin A, FASEB JOURNAL, 5256, Vol. 3, No. 4, (1989)	
	HH	<b>STARUCH ET AL</b> , FK506 and Rapamycin Inhibit Murine T Cell Activation Through Different Mechanisms, The FASEB Journal, Vol. 3, No. 3, 3411, (1989)	
	II	<b>J. ALEXANDRE et al</b> , Rapamycin and CCI-779, Bull. Cancer, 86 (10):808-11, XP-001078856 (October 1999)	
	JJ	<b>A. PERREN ET AL</b> , Immunohistochemical Evidence of Loss of PTEN Expression in Primary Ductal Adenocarcinomas the Breast, AM. J. Pathology, 155, (4):1253-60, (October 1999)	
	KK	<b>J.E. DANCEY ET AL</b> , Rapamycin-Sensitive Signal-Transduction Pathways: Protein Translation Control of Cell Proliferation, ASCO Educational Book, pp. 68-75, Spring 2000	
	LL	<b>M. HIDALGO ET AL</b> , The Rapamycin-Sensitive Signal Transduction Pathway as a Target for Cancer Therapy, Oncogene, 19, pp. 6680-6686, (December 27, 2000)	
	MM	<b>E.A. SAUSVILLE ET AL</b> , New Agents-Noncytotoxins, Antiangiogenesis, VON-Genetics Institute, ASCO Educational Book, Fall 1998, pp. 112-117	

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				Attorney Docket Number	AM101323USA
Sheet	4	of	6		

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	NN	<b>T. SCHMELZLE ET AL</b> , TOR, a Central Controller of Cell Growth, Cell, vol.103, pp. 253-262, (October 13, 2000)	
	OO	<b>J. ALEXANDRE ET AL</b> , CCI-779, A New Rapamycin Analog, has Antitumor Activity at Doses Inducing only Mild Cutaneous Effects and Mucositis; Early Results of an Ongoing Phase 1 Study, Proceedings of the 10 <sup>th</sup> NCI/EORTC/AACR Symposium, (1999) (Poster Presentation)	
	PP	<b>J. GIBBONS ET AL</b> , The Effect of CCI-779, A Novel Macrolide Anti-Tumor Agent, on the Growth of Human Tumor Cells In Vitro and In Nude Mouse Xenografts In Vivo, Proceedings of the American Association for cancer Research, 301a, 40, (March 1999)	
	QQ	<b>B. GEORGER ET AL</b> , Proceedings of the American Association for Cancer Research, (1999), 603a, 40	
	RR	<b>J. ALEXANDRE ET AL</b> , Phase 1 Study of CCI-779 a Novel Rapamycin Analog Preliminary Results, Proceedings of the American Association for Cancer Research, 613, 41, (March 2000)	
	SS	<b>M. HIDALGO ET AL</b> , Phase 1 and Pharmacological Study of CCI-779, A Cell Cycle Inhibitor, Clinical Cancer Research, Proceedings of the 11 <sup>th</sup> NCI/EORTC/AACR Symposium, 4548s, 6, (November 2000)	
	TT	<b>M. HIDALGO ET AL</b> , A Phase 1 and Pharmacological Study of CCI-779, a Rapamycin Ester Cell Cycle Inhibitor, Annuals of Oncology, 133a, 11 (4), (October 2000)	
	UU	<b>E. RAYMOND ET AL</b> , CCI-779, an Ester Analog of Rapamycin that Interacts with PTEN/PI3 Kinase Pathways: A Phase Study utilizing a Weekly intravenous Schedule, Clinical Cancer Research, Proceedings of the 11 <sup>th</sup> NCI/EORTC/AACR Symposium, Ab. 414, Vol. 6, (November 2000)	
	VV	<b>E. RAYMOND ET AL</b> , CCI-779, A Rapamycin Analog with Antitumor Activity: A phase I Study Utilizing a Weekly Schedule, Proceedings of ASCO, 187a, Vol. 19, (2000)	
	WW	<b>M. HIDALGO ET AL</b> , Phase 1 and Pharmacological Studies with the Rapamycin Analog CCI-779 Administered as a 30 Minute Fusion, NCI-CTEP Drug Development Meeting, October 1999	
	XX	<b>M. ABOU-GHARBIA ET AL</b> , Medicinal Chemistry Approaches for Optimization of Early Leads in Drug Candidates: The Discovery of Calicheamicin, Rapamycin and EAA-090, International Conference on Pure and Applied Heterocyclic Chemistry, (March 2000)	
	YY	<b>R. LANGRETH ET AL</b> , Drug Progress on hard-to-Treat Cancers is Cited, The Wall Street Journal, Vol. 234, (November 17, 1999)	
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	ZZ	<b>GEORGER ET AL</b> , Antitumor Acitivity of the Rapamycin Analog CCI-779 in Human Primitive Neuroectodermal Tumor/Medulloblastoma Models as Single Agent and in Combination Chemotherapy, Cancer Research, Vol. 61, No. 4, pp. 1527-1532, (February 15, 2001),	
	AAA	<b>SCHWARTSMANN G. ET AL</b> , Marine organisms and other novel Natural Sources of New Cancer Drugs, Annals of Oncology, Vol. 11, No. 3, pp. 235-243, (October 13, 2000)	
	BBB	<b>CARTER ET AL</b> , Chemotherapy of Cancer, Second edition, John Wiley & Sons, N.Y. N.Y. (1981), pp. 362-365	
	CCC	<b>TSAI ET AL</b> , Combination Cytotoxic Effects of Cis-Diamminedichloroplatinum (II) and 5-Fluorouracil with and without Leucovorin against Human Non-small Cell Lung Cancer Cell Lines, Cancer Res. 53, (5), pp. 1079-84 (1993) Abstract only	
	DDD	<b>ENG, C. P. ET AL</b> , Activity of Rapamycin (AY-22,989) Against Transplanted Tumors, The Journal of Antibiotics, Vol. 37, No. 10, pp. 1231-1237, (October 1984)	
	EEE	<b>PUNT, C.J. ET AL</b> , A Phase 1 Study of Escalating Doses of CCI-779 in combination with 5-Fluorouracil and Leucovorin in Patients with Advanced Solid Tumors, European Journal of Cancer, Vol. 37, No. Supplement 6, pg. S17, (October 2001)	
	FFF	<b>BONI, J. ET AL</b> , Pharmacokinetics of Escalting Doses of CCI-779 in Combination with 5-Fluorouracil and Leucovorin in Patients with Advanced Solid Tumors, European Journal of Cancer, Vol. 37, No. Supplemental 6, Page S68, (October 2001)	
	GGG	<b>GUPTA ET AL</b> , Combinations for Cancer Prevention, Nature Medicine, Vol. 6, No. 9, (September 2000)	
	HHH	<b>GREENBERGER ET AL</b> , A New Irreversible Inhibitor of Epidermal Growth Factor Receptor Tyrosine Kinase for the Treatment of Cancer, Clinical Cancer Research, Vol. 6, pg. 38 (November 2000)	
	III	<b>TORRANCE ET AL</b> , Combinatorial Chemoprevention of Intestinal Neoplasia, Nature Medicine, Vol. 6, pg. 8, (September 2000)	
	JJJ	<b>SHI ET AL</b> , Rapamycin Enhances Apoptosis and Increases Sensitivity to Cisplatin in Vitro, Cancer Research, 55, pgs. 1982-1988, (May 1, 1995)	
	KKK	<b>DORLAND'S</b> Illustrated Medical Dictionary, p. 987, (1965)	

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